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The benchmark for custom radiation therapy

K123015

NOV 21 2012

Section 5	510(k) Summary

Section 807.87 (h) A 510(k) Summary as described in Section 807.92

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

September 26, 2012

Submitter's Name:

.decimal, Inc.
121 Central Park Pl
Sanford, Florida 32771

Contact Person:

Kimberly Rupp
Quality and Regulatory Affairs Manager
Phone: 407-330-3300
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Device Name:

.decimal Photon Block

Classification Name:

IXI
21 CFR 892.5710 "Radiation Therapy Beam Shaping Block"
Class II

Device Description:

The .decimal Photon Block is a Cerrobend block (or material with similar attenuating properties) with a 2D pattern/hole made from it, which defines the area that is to be treated with a photon beam. The design for a .decimal Photon Block is generated out of a customer's treatment planning system (TPS) or physician's specifications and is unique to each patient. The device functions as a beam shaping block. The block fits into a

customer's linear accelerator. As radiation is passed through the collimator, the beam passes through cerrobend and it will be blocked. The opening of the photon block where there is no cerrobend, the radiation will pass through targeted area defined by the radiation therapy professional. The operating principles are explained in section 12 of this submittal.

Predicate Device(s):

.decimal Electron Aperture (K111759), .decimal Inc.

Intended Use:

.decimal's Photon Block manufacturing service manufactures Photon Blocks for external beam photon radiation therapy. The Photon Block is designed by the customer's treatment planning system or physician specifications to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Photon Blocks are intended for use by healthcare professionals.

Indications for Use:

In IMRT therapy for cancer, a photon beam is aimed at the cancerous tissue using a linear accelerator. The linear accelerator is rotated around the patient while the patient lies on a treatment table; the linear accelerator consists of the gantry, which rotates around the patient. The gantry contains a collimator, which points at pre-determined positions to maximize efficiency and dose delivery to the tumor volume. Each gantry angle, or "port", requires custom-made, beam modifying, patient specific devices called: ***Photon Block***.

The Photon Block is inserted into the gantry's collimator to shape and focus the beam as it exits the gantry en route to the targeted area. The *photon block* is also called a cerrobend block, which defines the area that is to be treated with the photon beam. Photon Blocks are generated out of the treatment planning system or physician's specifications and are unique to each patient and each gantry angle.

Summary of Technological Characteristics:

The device features of the .decimal Photon Block are similar to the predicate device (.decimal Electron Aperture K111759 cleared in 2011). They both are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. Whereas the previous version was made using brass used solely in proton radiation therapy, this version is made using cerrobend and is used for photon radiation therapy. Like .decimal Apertures used in proton therapy, each .decimal Photon Block must be validated and approved by the radiation therapy professional prior

to use on a patient. The target population is identical and the use parameters are also very similar.

A detailed comparison can be found in section 10 of this submittal.

Summary of Non-Clinical Testing:

Clinical testing was not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Clinically oriented validation test cases were written and executed in house by .decimal personnel including a Board Certified Medical Physicist where Photon Blocks were deemed safe and effective for clinical use. The tests show that .decimal Photon Blocks performed as well as the predicate device. A declaration of conformity to this requirement can be found in section 18 of this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO-66
Silver Spring, MD 20993-002

November 21, 2012

Ms. Kym Rupp
Quality & Regulatory Affairs Manager
.decimal, Inc.
121 Central Park Place
SANFORD FL 32771

Re: K123015
Trade/Device Name: .DECIMAL Photon Block
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping device
Regulatory Class: II
Product Code: IXI
Dated: September 26, 2012
Received: September 28, 2012

Dear Ms. Rupp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara 2012.12.03 07:27:41 -05'00'

Janine M. Morris
Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K123015

Device Name: .decimal Photon Block

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

William Jung 2012.11.21 13:54:00 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____**K123015**_____